



## General

### Guideline Title

Vitamin D and calcium supplementation to prevent fractures in adults: U.S. Preventive Services Task Force recommendation statement.

### Bibliographic Source(s)

U.S. Preventive Services Task Force (USPSTF). Vitamin D and calcium supplementation to prevent fractures in adults: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2013 May 7;158(9):691-6. [12 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

## Recommendations

### Major Recommendations

The U.S. Preventive Services Task Force (USPSTF) grades its recommendations (A, B, C, D, or I) and identifies the levels of certainty regarding net benefit (High, Moderate, and Low). The definitions of these grades can be found at the end of the "Major Recommendations" field.

#### Summary of Recommendations and Evidence

The USPSTF concludes that the current evidence is insufficient to assess the balance of the benefits and harms of combined vitamin D and calcium supplementation for the primary prevention of fractures in premenopausal women or in men. (I statement)

The USPSTF concludes that the current evidence is insufficient to assess the balance of the benefits and harms of daily supplementation with greater than 400 IU of vitamin D<sub>3</sub> and greater than 1000 mg of calcium for the primary prevention of fractures in noninstitutionalized postmenopausal women. (I statement)

The USPSTF recommends against daily supplementation with 400 IU or less of vitamin D<sub>3</sub> and 1000 mg or less of calcium for the primary prevention of fractures in noninstitutionalized postmenopausal women. (D recommendation)

#### Clinical Considerations

##### Patient Population Under Consideration

This recommendation applies to noninstitutionalized or community-dwelling asymptomatic adults without a history of fractures. "Community-dwelling" is defined as not living in an assisted living facility, nursing home, or other institutional care setting. This recommendation does not apply to persons with osteoporosis or vitamin D deficiency.

## Considerations for Practice Regarding the I Statements

### *Potential Preventable Burden*

The health burden of fractures is substantial in the older adult population.

### *Potential Harms*

In the Women's Health Initiative (WHI), a statistically increased incidence of renal stones occurred in women taking supplemental vitamin D and calcium. One woman was diagnosed with a urinary tract stone for every 273 women who received supplementation over a 7-year follow-up.

### *Costs*

Vitamin D and calcium supplements are inexpensive and readily available without a prescription.

### *Current Practice*

Vitamin D and calcium supplementation are often recommended for women, especially postmenopausal women, to prevent fractures. Surveys estimate that 56% of women aged 60 years or older take supplemental vitamin D and 60% take a supplement containing calcium. The exact dosage is not well-known.

### *Other Approaches to Prevention*

The USPSTF recommends screening for osteoporosis in women aged 65 years or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors. This recommendation statement is available on the [USPSTF Web site](#); see also the National Guideline Clearinghouse (NGC) summary of the USPSTF guideline [Screening for osteoporosis: U.S. Preventive Services Task Force recommendation statement](#).

The USPSTF recommends vitamin D supplementation (the median dose of vitamin D in available studies was 800 IU) to prevent falls in community-dwelling adults aged 65 years or older who are at increased risk for falls because of a history of recent falls or vitamin D deficiency (B recommendation). This recommendation statement is available on the [USPSTF Web site](#); see also the NGC summary of the USPSTF guideline [Prevention of falls in community-dwelling older adults: U.S. Preventive Services Task Force recommendation statement](#).

### Definitions:

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be measured.	Read "Clinical Considerations" section of USPSTF Recommendation Statement (see the "Major Recommendations" field). If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

## USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines *certainty* as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:</p> <ul style="list-style-type: none"><li>• The number, size, or quality of individual studies</li><li>• Inconsistency of findings across individual studies</li><li>• Limited generalizability of findings to routine primary care practice; and</li><li>• Lack of coherence in the chain of evidence</li></ul> <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>
Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"><li>• The limited number or size of studies</li><li>• Important flaws in study design or methods</li><li>• Inconsistency of findings across individual studies</li><li>• Gaps in the chain of evidence</li><li>• Findings not generalizable to routine primary care practice; and</li><li>• A lack of information on important health outcomes</li></ul> <p>More information may allow an estimation of effects on health outcomes.</p>

## Clinical Algorithm(s)

None available

## Scope

## Disease/Condition(s)

Bone fractures in adults

## Guideline Category

Assessment of Therapeutic Effectiveness

Prevention

## Clinical Specialty

Family Practice

Geriatrics

Internal Medicine

Obstetrics and Gynecology

Preventive Medicine

## Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Nurses

Physician Assistants

Physicians

Public Health Departments

## Guideline Objective(s)

To assess the balance of the benefits and harms of combined vitamin D and calcium supplementation for the primary prevention of fractures in adults

## Target Population

Non-institutionalized or community-dwelling asymptomatic adults without a history of fractures

Note: This recommendation does not apply to the treatment of persons with osteoporosis or vitamin D deficiency.

## Interventions and Practices Considered

Vitamin D and calcium supplementation

## Major Outcomes Considered

Key Question 1: What are the effects of vitamin D with or without calcium supplements on the clinical outcome of fractures in randomized, controlled trials (RCTs)? (overarching question)

Key Question 2: What are the associations between vitamin D status and the clinical outcome of fractures in observational studies?

Key Question 3: What are the effects of vitamin D with or without calcium supplements on the net changes in vitamin D status in RCTs?

Key Question 4: What are the adverse outcomes associated with vitamin D and calcium supplements in RCTs?

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): A meta-analysis was prepared by the Tufts Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

### Data Sources and Searches

In the 2009 evidence report, EPC staff searched MEDLINE and the Cochrane Central Register of Controlled Trials through April 2009 for primary studies of any design. Search terms included *vitamin D*, *25-hydroxyvitamin D*, *calcium*, and text terms and Medical Subject Heading terms related to fracture and bone mineral density. Searches were limited to articles about human participants published in English-language journals. The complete search strategies have been published elsewhere (see Evidence Report/Technology Assessment, No. 183 [see the "Availability of Companion Documents" field]). EPC staff updated specific searches for fracture outcomes through July 2011.

### Study Selection and Outcomes of Interest

Clinical outcomes of interest included incidence of any fracture at any site (for example, hip, spine, or wrist). EPC staff recorded whether the outcomes were primary or secondary end points in the original article.

For benefits and harms of vitamin D supplementation (key questions [KQs] 1 and 4), EPC staff included randomized, controlled trials (RCTs) of generally healthy adults (<20% of study participants had major chronic diseases, such as diabetes or cardiovascular disease, at baseline) that compared vitamin D supplementation with or without calcium against no supplementation or placebo for the outcomes of interest. For the purpose of the review, EPC staff excluded studies that enrolled pregnant women only or measured vitamin D status only during pregnancy and RCTs comparing different dosages of vitamin D supplementation without a control group that did not receive vitamin D supplementation. To include available data on elderly persons (aged  $\geq 65$  years), EPC staff also accepted RCTs of older ambulatory adults with any disease other than cancer. They excluded short-term (<1 month) RCTs and trials that used synthetic vitamin D analogues (for example, oxacalcitriol or paricalcitol).

For associations between vitamin D status and outcomes (KQ 2), a large number of RCTs reporting fracture outcomes met the eligibility criteria; therefore, EPC staff decided not to update the observational studies of the associations of vitamin D status and fracture outcomes, instead referring to the Ottawa evidence report (which is current up to 2005) for this question.

For effects of vitamin D supplementation on changes in vitamin D status (KQ 3), EPC staff adopted the results from the 2009 evidence report and did not update the search.

## Number of Source Documents

Data from 137 studies were included.

## Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

## Rating Scheme for the Strength of the Evidence

Not applicable

## Methods Used to Analyze the Evidence

Meta-Analysis of Randomized Controlled Trials

## Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): A meta-analysis was prepared by the Tufts Evidence-based Practice Center (EPC) for use by the U.S. Preventive Services Task Force (USPSTF) (see the "Availability of Companion Documents" field).

### Data Extraction and Quality Assessment

For all eligible randomized, controlled trials (RCTs) and observational studies in the present update, EPC staff extracted data on study characteristics, participant characteristics, details on vitamin D and calcium supplements, baseline vitamin D status (including assay used, definition of outcomes, and study results). For RCTs, the number of events and total number of participants in each group were extracted to calculate effect sizes. For observational studies, EPC staff selected the results from the full statistical model that adjusted for the largest number of potential confounders and recorded the number of cases and total number at risk (for cohort studies) or controls (for nested case-control studies) for each blood 25-(OH)D category, if reported. All quantitative data were verified by a second reviewer. For observational studies, EPC staff also listed the confounders adjusted for in the study design (for example, matching factors) or analyses.

EPC staff used the Agency for Healthcare Research and Quality Methods Reference Guide for Effectiveness Reviews criteria to grade study methodologic quality as good, fair, or poor. For RCTs, EPC staff applied quality items described in the CONSORT (Consolidated Standards of Reporting Trials) statement. For observational studies, they applied quality items described in the STROBE (Strengthening the Reporting of Observational studies in Epidemiology) statement, and specific items concerning the background vitamin D exposure, adjustment for potential confounding factors, and clarity of reporting of vitamin D status assessments and statistical analyses. For each included study, 1 reviewer rated study quality, which was confirmed by at least 1 other reviewer. Disagreements were resolved by consensus.

### Data Synthesis

For analyses of RCTs included for key question (KQ) 1, EPC staff used the DerSimonian-Laird random-effects model meta-analysis to examine the effects of vitamin D with or without calcium supplements on fractures. Most of these studies reported more than 1 fracture outcome. EPC staff selected 1 fracture outcome from each study to be included in the meta-analyses based on the descending order of most reported outcomes: total fracture, hip fracture, and nonvertebral fracture. They tested for heterogeneity with the Cochran Q statistic (considered significant when the *P* value was less than 0.10) and quantified the extent of heterogeneity with the  $I^2$  index. EPC staff defined low, moderate, and high heterogeneity as  $I^2$  values of 25%, 50%, and 75%, respectively. These cutoffs are arbitrary and were used for descriptive purposes only.

EPC staff reported the effects of combined vitamin D and calcium supplementation separately from vitamin D supplementation alone on fracture outcomes. Subgroup analyses were performed to evaluate the influences of study populations (that is, institutionalized or community-dwelling adults) on the pooled effect estimates. The Z test was used to test the difference in estimates of pooled effects between subgroups. EPC staff also used random-effects meta-regression (fitted with restricted maximum likelihood) to explore whether the effects of vitamin D supplementation on fracture outcomes depends on 2 factors: daily dose of vitamin D supplementation and baseline blood 25-(OH)D concentration.

Analyses were conducted by using Stata SE 11 software (StataCorp, College Station, Texas). All *P* values were 2-tailed, and a *P* value less than 0.05 was considered to indicate a significant difference, unless otherwise specified.

## Methods Used to Formulate the Recommendations

### Balance Sheets

### Expert Consensus

## Description of Methods Used to Formulate the Recommendations

The U.S. Preventive Services Task Force (USPSTF) systematically reviews the evidence concerning both the benefits and harms of widespread implementation of a preventive service. It then assesses the certainty of the evidence and the magnitude of the benefits and harms. On the basis of this assessment, the USPSTF assigns a letter grade to each preventive service signifying its recommendation about provision of the service (see Table below). An important, but often challenging, step is determining the balance between benefits and harms to estimate "net benefit" (that is,

benefits minus harms).

Table 1. U.S. Preventive Services Task Force Recommendation Grid\*

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	Moderate	Small	Zero/Negative
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient			

\*A, B, C, D, and I (*Insufficient*) represent the letter grades of recommendation or statement of insufficient evidence assigned by the U.S. Preventive Services Task Force after assessing certainty and magnitude of net benefit of the service (see the "Rating Scheme for the Strength of the Recommendations" field).

The overarching question that the Task Force seeks to answer for every preventive service is whether evidence suggests that provision of the service would improve health outcomes if implemented in a general primary care population. For screening topics, this standard could be met by a large randomized, controlled trial (RCT) in a representative asymptomatic population with follow-up of all members of both the group "invited for screening" and the group "not invited for screening."

Direct RCT evidence about screening is often unavailable, so the Task Force considers indirect evidence. To guide its selection of indirect evidence, the Task Force constructs a "chain of evidence" within an analytic framework. For each key question, the body of pertinent literature is critically appraised, focusing on the following 6 questions:

1. Do the studies have the appropriate research design to answer the key question(s)?
2. To what extent are the existing studies of high quality? (i.e., what is the internal validity?)
3. To what extent are the results of the studies generalizable to the general U.S. primary care population and situation? (i.e., what is the external validity?)
4. How many studies have been conducted that address the key question(s)? How large are the studies? (i.e., what is the precision of the evidence?)
5. How consistent are the results of the studies?
6. Are there additional factors that assist the USPSTF in drawing conclusions (e.g., presence or absence of dose-response effects, fit within a biologic model)?

The next step in the Task Force process is to use the evidence from the key questions to assess whether there would be net benefit if the service were implemented. In 2001, the USPSTF published an article that documented its systematic processes of evidence evaluation and recommendation development. At that time, the Task Force's overall assessment of evidence was described as good, fair, or poor. The Task Force realized that this rating seemed to apply only to how well studies were conducted and did not fully capture all of the issues that go into an overall assessment of the evidence about net benefit. To avoid confusion, the Task Force has changed its terminology. Whereas individual study quality will continue to be characterized as good, fair, or poor, the term certainty will now be used to describe the Task Force's assessment of the overall body of evidence about net benefit of a preventive service and the likelihood that the assessment is correct. Certainty will be determined by considering all 6 questions listed above; the judgment about certainty will be described as high, moderate, or low.

In making its assessment of certainty about net benefit, the evaluation of the evidence from each key question plays a primary role. It is important to note that the Task Force makes recommendations for real-world medical practice in the United States and must determine to what extent the evidence for each key question—even evidence from screening RCTs or treatment RCTs—can be applied to the general primary care population. Frequently, studies are conducted in highly selected populations under special conditions. The Task Force must consider differences between the general primary care population and the populations studied in RCTs and make judgments about the likelihood of observing the same effect in actual practice.

It is also important to note that one of the key questions in the analytic framework refers to the potential harms of the preventive service. The Task Force considers the evidence about the benefits and harms of preventive services separately and equally. Data about harms are often obtained from observational studies because harms observed in RCTs may not be representative of those found in usual practice and because some harms are not completely measured and reported in RCTs.

Putting the body of evidence for all key questions together as a chain, the Task Force assesses the certainty of net benefit of a preventive service by asking the 6 major questions listed above. The Task Force would rate a body of convincing evidence about the benefits of a service that, for example, derives from several RCTs of screening in which the estimate of benefits can be generalized to the general primary care population as "high" certainty (see the "Rating Scheme for the Strength of Recommendations" field). The Task Force would rate a body of evidence that was not clearly applicable to general practice or has other defects in quality, research design, or consistency of studies as "moderate" certainty. Certainty is "low" when, for example, there are gaps in the evidence linking parts of the analytic framework, when evidence to determine the harms of treatment is unavailable, or when evidence about the benefits of treatment is insufficient. Table 4 in the methodology document listed below (see the "Availability of Companion Documents" field) summarizes the current terminology used by the Task Force to describe the critical assessment of evidence at all 3 levels: individual studies, key questions, and overall certainty of net benefit of the preventive service.

Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med.* 2007;147:871-875.[5 references].

I Statements

For I statements, the USPSTF has a new plan to commission its Evidence-based Practice Centers to collect information in 4 domains pertinent to clinical decisions about prevention and to report this information routinely. This plan is described in the paper: Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. *Ann Intern Med.* 2009;150:199-205. [www.annals.org](http://www.annals.org)

The first domain is potential preventable burden of suffering from the condition. When evidence is insufficient, provision of an intervention designed to prevent a serious condition (such as dementia) might be viewed more favorably than provision of a service designed to prevent a condition that does not cause as much suffering (such as rash). The USPSTF recognized that "burden of suffering" is subjective and involves judgment. In clinical settings, it should be informed by patient values and concerns.

The second domain is potential harm of the intervention. When evidence is insufficient, an intervention with a large potential for harm (such as major surgery) might be viewed less favorably than an intervention with a small potential for harm (such as advice to watch less television). The USPSTF again acknowledges the subjective nature and the difficulty of assessing potential harms: for example, how bad is a "mild" stroke?

The third domain is cost—not just monetary cost, but opportunity cost, in particular the amount of time a provider spends to provide the service, the amount of time the patient spends to partake of it, and the benefits that might derive from alternative uses of the time or money for patients, clinicians, or systems. Consideration of clinician time is especially important for preventive services with only insufficient evidence because providing them could "crowd out" provision of preventive services with proven value, services for conditions that require immediate action, or services more desired by the patient. For example, a decision to routinely inspect the skin could take up the time available to discuss smoking cessation, or to address an acute problem or a minor injury that the patient considers important.

The fourth domain is current practice. This domain was chosen because it is important to clinicians for at least 2 reasons. Clinicians justifiably fear that not doing something that is done on a widespread basis in the community may lead to litigation. More important, addressing patient expectations is a crucial part of the clinician–patient relationship in terms of building trust and developing a collaborative therapeutic relationship. The consequences of not providing a service that is neither widely available nor widely used are less serious than not providing a service accepted by the medical profession and thus expected by patients. Furthermore, ingrained care practices are difficult to change, and efforts should preferentially be directed to changing those practices for which the evidence to support change is compelling.

Although the reviewers did not explicitly recognize it when these domains were chosen, the domains all involve consideration of the potential consequences—for patients, clinicians, and systems—of providing or not providing a service. Others writing about medical decision making in the face of uncertainty have suggested that the consequences of action or inaction should play a prominent role in decisions.

Rating Scheme for the Strength of the Recommendations

What the U.S. Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The USPSTF recommends the service. There is high certainty	Offer or provide this service.



Grade	Grade Definitions	Suggestions for Practice
	that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	
C	The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be measured.	Read "Clinical Considerations" section of USPSTF Recommendation Statement (see the "Major Recommendations" field). If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

### USPSTF Levels of Certainty Regarding Net Benefit

Definition: The USPSTF defines *certainty* as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	<p>The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as:</p> <ul style="list-style-type: none"> <li>• The number, size, or quality of individual studies</li> <li>• Inconsistency of findings across individual studies</li> <li>• Limited generalizability of findings to routine primary care practice; and</li> <li>• Lack of coherence in the chain of evidence</li> </ul> <p>As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.</p>
Low	<p>The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of:</p> <ul style="list-style-type: none"> <li>• The limited number or size of studies</li> <li>• Important flaws in study design or methods</li> <li>• Inconsistency of findings across individual studies</li> <li>• Gaps in the chain of evidence</li> <li>• Findings not generalizable to routine primary care practice; and</li> <li>• A lack of information on important health outcomes</li> </ul> <p>More information may allow an estimation of effects on health outcomes.</p>

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

# Method of Guideline Validation

Comparison with Guidelines from Other Groups

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

Peer Review. Before the U.S. Preventive Services Task Force (USPSTF) makes its final determinations about recommendations on a given preventive service, the Evidence-based Practice Center and the Agency for Healthcare Research and Quality send a draft evidence review to 4 to 6 external experts and to Federal agencies and professional and disease-based health organizations with interests in the topic. The experts are asked to examine the review critically for accuracy and completeness and to respond to a series of specific questions about the document. After assembling these external review comments and documenting the proposed response to key comments, the topic team presents this information to the USPSTF in memo form. In this way, the USPSTF can consider these external comments before it votes on its recommendations about the service. Draft recommendation statements are then circulated for comment among reviewers representing professional societies, voluntary organizations, and Federal agencies, as well as posted on the Task Force Web site for public comment. These comments are discussed before the final recommendations are confirmed.

Response to Public Comment. A draft version of this recommendation statement was posted for public comment on the USPSTF Web site from 12 June to 10 July 2012. The USPSTF received more than 40 comments. In response, information was added to the Rationale section to reinforce the basic dietary requirements for vitamin D and calcium. Several recently published studies on the benefits and harms of vitamin D and calcium supplementation were reviewed, and their results were highlighted in the Discussion section. The dose of calcium used in the WHI trial was clarified throughout the statement.

Comparison with Guidelines from Other Groups. Recommendations from the following groups were discussed: the Institute of Medicine and the World Health Organization.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is not specifically stated for each recommendation.

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Benefits of Preventive Medication

In premenopausal women and in men, there is inadequate evidence to determine the effect of combined vitamin D and calcium supplementation on the incidence of fractures. In postmenopausal women, there is adequate evidence that daily supplementation with 400 IU of vitamin D<sub>3</sub> combined with 1000 mg of calcium has no effect on the incidence of fractures. However, there is inadequate evidence about the effect of higher doses of combined vitamin D and calcium supplementation on fracture incidence in noninstitutionalized postmenopausal women.

### Potential Harms

Harms of Preventive Medication

Adequate evidence indicates that supplementation with 400 IU or less of vitamin D<sub>3</sub> and 1000 mg or less of calcium increases the incidence of renal stones. The USPSTF assessed the magnitude of this harm as small.

# Qualifying Statements

## Qualifying Statements

- The U.S. Preventive Services Task Force (USPSTF) makes recommendations about the effectiveness of specific clinical preventive services for patients without related signs or symptoms.
- It bases its recommendations on the evidence of both the benefits and harms of the service and an assessment of the balance. The USPSTF does not consider the costs of providing a service in this assessment.
- The USPSTF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation. Similarly, the USPSTF notes that policy and coverage decisions involve considerations in addition to the evidence of clinical benefits and harms.
- Recommendations made by the USPSTF are independent of the U.S. government. They should not be construed as an official position of the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

## Implementation of the Guideline

### Description of Implementation Strategy

The experiences of the first and second U.S. Preventive Services Task Force (USPSTF), as well as that of other evidence-based guideline efforts, have highlighted the importance of identifying effective ways to implement clinical recommendations. Practice guidelines are relatively weak tools for changing clinical practice when used in isolation. To effect change, guidelines must be coupled with strategies to improve their acceptance and feasibility. Such strategies include enlisting the support of local opinion leaders, using reminder systems for clinicians and patients, adopting standing orders, and audit and feedback of information to clinicians about their compliance with recommended practice.

In the case of preventive services guidelines, implementation needs to go beyond traditional dissemination and promotion efforts to recognize the added patient and clinician barriers that affect preventive care. These include clinicians' ambivalence about whether preventive medicine is part of their job, the psychological and practical challenges that patients face in changing behaviors, lack of access to health care or of insurance coverage for preventive services for some patients, competing pressures within the context of shorter office visits, and the lack of organized systems in most practices to ensure the delivery of recommended preventive care.

Dissemination strategies have changed dramatically in this age of electronic information. While recognizing the continuing value of journals and other print formats for dissemination, the USPSTF Task Force will make all its products available through its [Web site](#) . The combination of electronic access and extensive material in the public domain should make it easier for a broad audience of users to access USPSTF materials and adapt them for their local needs. Online access to USPSTF products also opens up new possibilities for the appearance of the annual, pocket-size *Guide to Clinical Preventive Services*.

To be successful, approaches for implementing prevention have to be tailored to the local level and deal with the specific barriers at a given site, typically requiring the redesign of systems of care. Such a systems approach to prevention has had notable success in established staff-model health maintenance organizations, by addressing organization of care, emphasizing a philosophy of prevention, and altering the training and incentives for clinicians. Staff-model plans also benefit from integrated information systems that can track the use of needed services and generate automatic reminders aimed at patients and clinicians, some of the most consistently successful interventions. Information systems remain a major challenge for individual clinicians' offices, however, as well as for looser affiliations of practices in network-model managed care and independent practice associations, where data on patient visits, referrals, and test results are not always centralized.

## Implementation Tools

Foreign Language Translations

Mobile Device Resources

Patient Resources

Pocket Guide/Reference Cards

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Staying Healthy

### IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

U.S. Preventive Services Task Force (USPSTF). Vitamin D and calcium supplementation to prevent fractures in adults: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med*. 2013 May 7;158(9):691-6. [12 references] [PubMed](#)

### Adaptation

Not applicable: The guideline was not adapted from another source.

### Date Released

2013 Feb 26

### Guideline Developer(s)

U.S. Preventive Services Task Force - Independent Expert Panel

### Guideline Developer Comment

The U.S. Preventive Services Task Force (USPSTF) is a federally-appointed panel of independent experts. Conclusions of the USPSTF do not necessarily reflect policy of the U.S. Department of Health and Human Services (DHHS) or DHHS agencies.

### Source(s) of Funding

The U.S. Preventive Services Task Force (USPSTF) is an independent, voluntary body. The U.S. Congress mandates that the Agency for

Healthcare Research and Quality support the operations of the USPSTF.

## Guideline Committee

U.S. Preventive Services Task Force (USPSTF)

## Composition of Group That Authored the Guideline

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*\*Members of the USPSTF at the time this recommendation was finalized. For a list of current Task Force members, go to <http://www.uspreventiveservicestaskforce.org/Page/Name/our-members> .*

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*Potential Conflicts of Interest*: None disclosed. Disclosure forms from USPSTF members can be viewed on the [Annals of Internal Medicine Web site](#) .

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .

## Availability of Companion Documents

The following are available:

Evidence Reviews:

- Chung M, Lee J, Terasawa T, Lau J, Trikalinos TA. Vitamin D with or without calcium supplementation for prevention of cancer and fractures: an updated meta-analysis for the U.S. Preventive Services Task Force. *Ann Intern Med*. 2011 Dec 20;155(12):827-38.
- Chung M, Balk EM, Brendel M, et al. Vitamin D and calcium: a systematic review of health outcomes. Evidence Review/Technology Assessment No. 183. AHRQ Publication No. 09-E015. Rockville, MD: Agency for Healthcare Research and Quality, 2009 Aug.

Electronic copies: Available from the [U.S. Preventive Services Task Force \(USPSTF\) Web site](#) .

#### Background Articles:

- Barton MB et al. How to read the new recommendation statement: methods update from the U.S. Preventive Services Task Force. *Ann Intern Med* 2007;147:123-127.
- Guirgis-Blake J et al. Current processes of the U.S. Preventive Services Task Force: refining evidence-based recommendation development. *Ann Intern Med* 2007;147:117-122.
- Sawaya GF et al. Update on the methods of the U.S. Preventive Services Task Force: estimating certainty and magnitude of net benefit. *Ann Intern Med* 2007;147:871-875.
- Petitti DB et al. Update on the methods of the U.S. Preventive Services Task Force: insufficient evidence. *Ann Intern Med*. 2009;150:199-205.

Electronic copies: Available from the [USPSTF Web site](#) .

#### The following are also available:

- Vitamin D and calcium supplementation to prevent fractures in adults. Clinical summary of U.S. Preventive Services Task Force recommendation. 2013 Feb. Electronic copies: Available from the [USPSTF Web site](#) .
- The guide to clinical preventive services, 2012. Recommendations of the U.S. Preventive Services Task Force. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2012. 128 p. Electronic copies available from the [AHRQ Web site](#) . See the related QualityTool summary on the [Health Care Innovations Exchange Web site](#) .
- A continuing medical education (CME) activity is available from the [Annals of Internal Medicine Web site](#) .

The [Electronic Preventive Services Selector \(ePSS\)](#)  is an application designed to provide primary care clinicians and health care teams timely decision support regarding appropriate screening, counseling, and preventive services for their patients. It is based on current recommendations of the USPSTF and can be searched by specific patient characteristics such as age, sex, and selected behavioral risk factors.

## Patient Resources

#### The following are available:

- Vitamin D and calcium supplementation to prevent fractures. Understanding task force recommendations. U.S. Preventive Services Task Force. Consumer fact sheet. 2013 Feb. 4 p. Electronic copies: Available from the [U.S. Preventive Services Task Force \(USPSTF\) Web site](#) .
- Vitamin D and calcium supplementation to prevent fractures in adults: U.S. Preventive Services Task Force recommendation statement. Summary for patients. *Ann Intern Med*. 2013 May;158(9):I-36. Electronic copies: Available from the [Annals of Internal Medicine Web site](#) .
- Women: stay healthy at any age. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 10-IP002-A. 2010 Aug. 2 p. Electronic copies: Available in PDF in [English](#)  and [Spanish](#)  from the AHRQ Web site. See the related QualityTool summary on the [Health Care Innovations Exchange Web site](#) .
- Men: stay healthy at any age. Rockville (MD): Agency for Healthcare Research and Quality. AHRQ Pub. No. 10-IP004-A. 2010 Aug. 2 p. Electronic copies: Available in PDF in [English](#)  and [Spanish](#)  from the AHRQ Web site. See the related QualityTool summary on the [Health Care Innovations Exchange Web site](#) .

Print copies: Available in English and Spanish from the Agency for Healthcare Research and Quality (AHRQ) Publications Clearinghouse. For more information, go to <http://www.ahrq.gov/research/publications/index.html>  or call 1-800-358-9295 (U.S. only).

Myhealthfinder is a new tool that provides personalized recommendations for clinical preventive services specific to the user's age, gender, and pregnancy status. It features evidence-based recommendations from the USPSTF and is available at [www.healthfinder.gov](http://www.healthfinder.gov)

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Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a

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## NGC Status

This NGC summary was completed by ECRI Institute on May 21, 2013. The information was verified by the guideline developer on May 29, 2013.

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